PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	19.07.2004
Applicant's or agent's file reference: SCB 790 PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/05550	27.05.2003	04.06.2002

Applicant
ABIOGEN PHARMA S.P.A. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SCB 790 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/05550	International filing date *(day/month/year)* 27.05.2003	Priority date *(day/month/year)* 04.06.2002
International Patent Classification (IPC) or both national classification and IPC A61K7/42		
Applicant ABIOGEN PHARMA S.P.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.12.2003	19.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Houyvet, C Telephone No. +49 89 2399-7506

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/05550

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-8 filed with telefax on 06.05.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 9

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7-8
	No:	Claims	1-6
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-8
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item I : Basis of the report

6. Basis for "as UV filter" inserted in new claim 1 is not found in the description as required by Rule 70.2(c) PCT. Therefore, new claim 1 will only be examined with regard to the "use of dolichol for the preparation of cosmetic and dermatological compositions designed to.... sunlight".

Re Item V : Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents :

D1 : PATENT ABSTRACTS OF JAPAN vol. 011, no. 163 (C-424),1987 & JP 61 293905 A (KANEBO LTD), 1986
D2 : PATENT ABSTRACTS OF JAPAN vol. 011, no. 379 (C-463), 1987 & JP 62 148415 A (KANEBO LTD), 1987
D3 : US-A-4 812 443
D4 : EP-A-0 149 847
D5 : EP-A-0 095 133
D6 : US-A-5 575 994
D7 : US-B1-6 261 575, cited in the application
D8 : DINI B ET AL.; EXPERIMENTAL GERONTOLOGY, vol. 37, no. 1, December 2001, pages 99-105, XP001154275, cited in the application

Unless otherwise stated, reference is made to the relevant passages cited in the International Search Report for each of these documents.

V.2.1.

a) D1 describes the use of dolichol in a cosmetic preparation for preventing skin ageing. The dolichol concentration ranging from 0.01-3 wt%. Thus, claims 1-3 and 6 are not new in view of D1 (Article 33(2) PCT).

D2 describes a composition containing 0.005-3 or 0.05-1 wt% of dolichol for the promotion of hair growth. The composition being formulated in different dosage form such as tonic, lotion and cream. Thus, claims 1-3 and 6 are not new in view of D2 (Article 33(2) PCT).
The International Preliminary Examination Authority can not take position on the

novelty of claims 4-5 and 7-8 with regard to D1 and D2, since these documents are only abstracts.

D3 describes a dolichol composition used for the treatment of anemia. In D3, the composition can contain 5 wt% of dolichol. Thus, claims 1-3 are not new in view of D3 (Article 33(2) PCT).

D4 describes the use of dolichol to treat hyperuricuria, hyperlipemia, arteriosclerosis, diabetes and hepatic diseases. D4 also states that dolichol is supposed to play an important role in life conservation of organisms and expected to be available as active ingredient for various pharmaceuticals. Thus claims 1-3 are not new in view of D4 (Article 33(2) PCT).

D7 also describes the use of vitamin E as antioxidant, and dolichol as an auxiliary factor of aerobic cellular energy metabolism in a sterol/ubiquinone composition for skin anti-ageing (i.e. for skin being aged by light, or for treatment of damage caused by light-ageing). Thus, claims 1, 4-6 are not new in view of D7 (Article 33(2) PCT).

b) D5 describes a method to prepare polyprenoids having the same configuration as dolichol and being useful as starting materials for the synthesis of the latter. Like D4, D5 states that dolichol is very important for the sustaining of lives in organisms and could be used for the retarding or prevention of ageing.

D6 describes anti-ageing compositions in the form of lotions, creams, milks, ointments, oils, ampoules, masks, gels, pads or sprays, and containing among others: vitamin E and/or F as antioxidants.

D8 sates that dolichol might have a role as scavenger of free radicals in the lipophylic environment inside the membranes, and that it accumulates in tissues during ageing.

c) Thus, only claims 7-8 appear new in view of D1-D7 (Article 33(2) PCT). However, these two claims do not involve an inventive step since the formulation of a pharmaceutical composition belongs to routine optimization tasks for the man skilled in the art. Carbon dioxide is also a common known propellant for sprays (Article 33(3) PCT).

V.2.2.

The feature of claim 3 is not referred to in the description. Claim 3 is therefore not supported by the description as required by Article 6 PCT. Indeed, the concentration

range found in claim 3 reads "0.002 and 5% by weight", whereas the description on page 4, line 24 reads : "0.02 and 5% weight".

Enclosure 1

CLAIMS (amended)

1. Use of dolichol as UV filter for the preparation of cosmetic and dermatological compositions designed to prevent acute and chronic skin damage caused by exposure to sunlight.

2. The use according to claim 1, wherein dolichol concentration is between 0.001 and 7% by weight.

3. The use according to claim 2, wherein dolichol concentration is between 0.002 and 5% by weight.

4. The use according to any one of the preceding claims, wherein dolichol is associated with other fat-soluble vitaminic active ingredients possessing an anti-radical action and/or with plant polyprenoids.

5. The use according to claim 4, wherein the fat-soluble vitaminic active ingredients with an anti-radical action are Vitamin E and Vitamin F and/or plant polyprenoids.

6. The use according to any one of claims 1-5, the composition being in the form of creams, lotions, milks, ointments, oils, ampoules, sticks and sprays.

7. The use according to claim 6, the composition being in spray form.

8. The use according to claim 7, wherein the propellant is carbon dioxide.